Louisiana Office of Public Health Laboratories	
Test Name	Hepatitis B Surface Antigen EIA
PHL Location	Office of Public Health Laboratory Baton Rouge
CPT Code	87340
Synonyms	HBsAg, Hep B Surface antigen
Brief Description of Test	The HBsAg EIA is used to detect for circulating Hepatitis B Surface Antigen (HBsAg) in human serum. It is used as a detection method for early acute or chronic hepatitis B infection.
Possible Results	Nonreactive Reactive
Reference Range	Nonreactive
Specimen Type	Serum
Specimen Container(s):	Red top tubes, Marble top tubes, polypropylene vials
Minimum volume accepted:	300 µL (does not allow for repeat testing or confirmatory testing)
Collection Instructions	Specimens should only be collected by personnel that have been properly trained. Care should be taken during specimen collection and handling to avoid generation of aerosols. Blood should be collected in a plastic tube, such as a vacutainer, which does not contain an anticoagulant. The collection tube may or may not contain a serum separator. If collected in a tube without serum separator, serum must be aliquoted into screw cap tubes before shipment to laboratory. Depending on the type of collection tube, the amount of time it will take for the blood to clot could take up to 60 minutes. Separation of serum from cells should take place within 2 hours of collection to prevent erroneous test results according to NCCLS guidelines. Follow the package insert for the collection tube you use. Label specimen with Patient Name and a 2nd unique identifier such as a chart number or medical record number. DOB is not considered unique. Complete a Lab Form 96 to accompany the serum sample. Lab submission form must be thoroughly completed with patient's first and last name, 2nd patient identifier, gender, date of birth, date of

	collection, time of collection, test requested, and submitter's name, address, and contact number. Two unique identifiers **MUST** be recorded on the tube **AND** the Lab 96 form. A missing identifier on the tube will be an automatic rejection. If the identifiers are missing from the Lab 96 form, the submitter must be contacted and a new form with this information must be faxed back to the lab before testing will take place. Transport specimen to laboratory as soon as possible after collection. Keep submission forms insulated from specimens.
Storage and Transport Instructions	Specimens can be shipped refrigerated (2-8°C) and can be stored for up to 7 days. For longer storage, serum should be poured into a sterile screw cap tube and be frozen at -20°C or colder. Frozen specimens must be shipped on dry ice and received at a temperature of -20°C or colder. If samples are frozen, document the date and time the sample was frozen.
Causes for Rejection	Unspun samples, tubes that contain less than 90% of the total drawing capacity (QNS), incorrect specimen type, or expired collection tubes must be rejected. Improper storage and improper transport temperature requirements are also reasons for rejection.
Limitations of the Procedure	A designation of reactive for HBsAg must not be based on a single reactive test result. Additional testing, such as confirmatory testing, is required to establish the specificity of any specimen reactive by the screening procedure. Initially reactive specimens must be retested in duplicate to validate the initial test results. If, after repeat testing, the absorbance values of both duplicate specimens are less than the cutoff value, the original specimen may be considered non-repeatedly reactive and negative for HBsAg. If, after repeat testing, the absorbance value of either of the duplicates is greater than or equal to the cutoff value, the specimen must be considered repeatedly reactive. A HBsAg Confirmatory Assay is performed on repeatedly reactive specimens. The specimen can be considered positive for HBsAg only if the HBsAg can be neutralized by the confirmatory procedure.
Interfering Substances	No clinically significant effect has been detected in assay results with increased levels of protein, lipids, bilirubin, or hemolysis, or after heat inactivation of patient samples.
References	BioRad Genetic Systems HBsAG EIA 3.0 package insert. EVOLIS™ Operator Manual
Additional Information	A HBsAg Confirmatory Assay is performed on repeatedly reactive specimens.

Release Date	03/15/2016
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